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BIOPROSTHETIC VALVE STENT

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The stent structure of the present invention would utilize an annular base ring defining an inflow orifice, with at least two circumferentially-spaced posts molded into the annular base ring at one end, and at their upper ends, molded into an upper ring comprising at least bi-segmented parabolic shaped scallops. The posts, which are constructed of spring steel molded in place, would provide the flextral capability necessary to allow relative movement between the scallops of the upper ring and the annular base. The parabolic-shaped segments taken together form a right cylinder of the inside diameter of the valve. The parabolic shape of the scallops reduce stress on the valve cusps.

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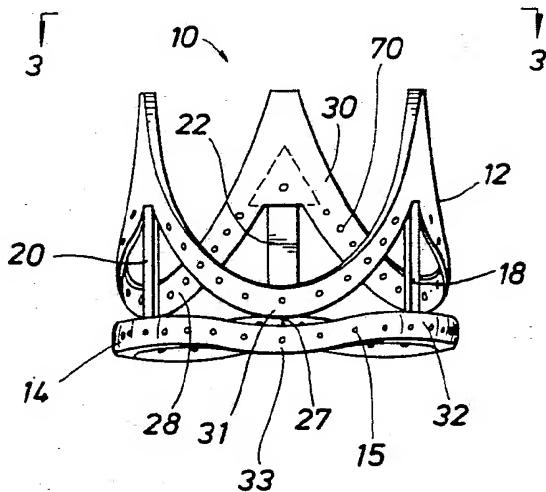
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## (54) Title: BIOPROSTHETIC VALVE STENT



## (57) Abstract

The stent structure of the present invention would utilize an annular base ring (14) defining an inflow orifice, with at least two circumferentially-spaced posts (18, 20) molded into the annular base ring at one end, and at their upper ends, molded into an upper ring (25) comprising at least bi-segmented parabolic shaped scallops (26, 28). The posts (18, 20), which are constructed of spring steel molded in place, would provide the flextral capability necessary to allow relative movement between the scallops of the upper ring and the annular base. The parabolic-shaped segments taken together form a right cylinder of the inside diameter of the valve. The parabolic shape of the scallops reduces stress on the valve cusps.

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## BIOPROSTHETIC VALVE STENT

SPECIFICATIONBACKGROUND OF THE INVENTION:1. Field Of The Invention:

5 The present invention relates to bioprosthetic valves. More particularly, the present invention relates to a valve stent, including an upper ring formed of multi-segmented parabolic-shaped scalloped rings, the valve stent formed of a polymer and spring steel composite structure.

2. General Background:

10 Valve prostheses have been utilized in surgical applications to replace various diseased or damaged natural valves, more particularly, heart valves including the aortic valve, the mitral valve and the tricuspid valve. In general, the failure of tissue heart valves have primarily been attributed to calcification and 15 premature degeneration of tissue used to fabricate the valve. Although reasons for calcification of the tissue in these devices are still not well understood it is believed that excessive mechanical stresses are 20 experienced by the tissue during their opening and closing function.

For example, in U.S. Patent No. 4,343,048 issued to Ross, et al, entitled "Stent For A Cardiac Valve," the patented stent includes a metal base ring having metal

legs projecting therefrom in a generally axial direction so that each of the legs can be resiliently deformed over substantially its whole axial length to take up strain in the valve without impairing its performance. The patent 5 stresses that the base ring of the stent would be substantially rigid so that as pressure conditions occur within the heart, the base ring would not deform to any substantial extent. In addition, each leg would be shaped so that as it would project from the base ring, it would 10 curve inwardly toward the axis of the stent in a "fishing rod structure" to avoid excessive stresses on the valve.

In recognizing problems in the present state of the art, an attempt to avoid valve failure has been the incorporation of a flexible polymer stent or valve frame. 15 However, even with the use of the polymer stents, permanent deformation of these frames or stents due to polymer creep often results in failure of tissue valves using plastic frames.

As will be appreciated from the following 20 description, it is possible in accordance with the present invention to provide a method to achieve complete flexibility of the valve frame without resulting polymer creep. A composite structure of polymer and spring steel is incorporated into the valve frame. Metal inserts of 25 spring steel are injection molded into place at 120° apart to form three vertical posts of the frame in the case of a tricuspid valve or 180° apart to form two vertical posts in the case of a bicuspid valve. The flex life of this spring steel under worse conditions of physiological 30 pressures would theoretically be infinite.

The frame would include an annular base ring defining an inflow orifice of the valve. If the valve is intended for use in the heart, this base ring is designed to proximate the physiological shape of the aortic valve 35 annulus. If the valve is intended for use in a vein, the base ring is designed to proximate the physiological shape of the inner annular wall of the vein or vessel. In the

preferred embodiment, there are molded into this ring three equally spaced frame posts joined by an upper ring comprising tri-segmented parabolic-shaped scallops. The upper scalloped ring defines generally three parabolic shaped one-third portions of the base between the center lines of the respective posts which together form a right cylinder of inside diameter of the valve. In the alternate embodiment, two oppositely spaced frame posts are molded into the base ring. The top of each frame post is joined by an upper ring comprising bi-segmented parabolic-shaped scallops. The parabolic shape of the scallops of the upper rings will reduce stress on the valve cusps. Cusp failure of existing tissue valves have been related generally to the ellipsoid shape of scalloping rings.

The scallops of the upper ring of the valve remain free and independent of the implant annulus to allow complete flexibility of the posts and the scallops. In the existing parabolic devices, the scallops form a part of the sewing ring which is tied down to the valve annulus during valve implantation thereby rendering the scalloping rings inflexible. This in turn would restrict the flex of the frame posts and expose valve cusps to higher stresses. In the present invention, the suture ring of the valve, which is constructed between the lower ring and the scallops of the upper ring, remains away and detached from cusp tissue.

The frame assembly may then be covered with fabric. Although this is not an essential feature, there are certain advantages to a fabric covered valve frame.

#### SUMMARY OF THE PRESENT INVENTION:

The bioprosthetic valve stent structure of the present invention would utilize an annular base ring defining the inflow orifice. In the preferred embodiment, three circumferentially-spaced posts are molded into the annular base ring at one end. At their upper ends is

5 molded an upper ring comprising tri-segmented parabolic shaped scallops. The alternate embodiment is composed of two oppositely spaced frame posts also molded at one end to the annular base and at their upper end to an upper ring comprising bi-segmented parabolic-shaped scallops. The posts, which are constructed of spring steel molded in place, would provide the flextral capability necessary to allow relative movement between the scallops of the upper ring and the annular base ring. The parabolic-shaped 10 segments taken together form a right cylinder of the inside diameter of the valve. The parabolic shape of the scallops reduce stress on the valve cusps. A suture ring would then be constructed between the annular ring and the scalloped upper ring.

15 BRIEF DESCRIPTION OF THE DRAWINGS:

In order that the invention may be more fully understood, embodiments in accordance therewith will now be described with reference to the accompanying drawings, wherein:

20 Figure 1 represents a front elevation view of the preferred embodiment of the present invention illustrating the parabolic shape of the upper ring of the valve stent;

25 Figure 2 is a side elevation view of the assembly of Figure 1, illustrating in full view one of the posts in the valve stent;

Figure 3 is an overall top view of the preferred embodiment of the valve stent of the present invention;

Figure 4 is a cross-sectional view along line 4 - 4 in Figure 3, illustrating a valve stent leg;

30 Figures 5 and 6 are front and side views respectively of the metallic leg portion of the preferred embodiment of the stent;

35 Figures 7 and 8 illustrate overall side and top views respectively of the preferred embodiment of the stent, following attachment of a tricuspid valve body and skirt portion;

Figure 9 is a cross-sectional view along line 9-9 in Figure 8;

Figure 10 represents an overall perspective view of an alternate embodiment of the present invention; and

5 Figure 11 is a side elevation view of the alternate embodiment shown in Figure 10.

#### DETAILED DESCRIPTION OF THE INVENTION

Figures 1-9 illustrate the preferred embodiment of the bioprosthetic valve stent of the present invention by 10 the numeral 10. As seen in Figures 1-9, more particularly Figures 1 and 2, valve stent 10 would comprise a valve frame assembly 12, with the valve frame assembly 12 including a lower most annular base ring 14, constructed as seen in top view in Figure 3, for defining the end flow 15 orifice 16 of the valve stent 10. Annular base ring 14, as seen in Figures 1 and 2, is designed, in the case of a heart valve, to substantially match the physiological aortic valve annulus shape corresponding to inflow orifice 16 of valve frame 12. In the case of a vascular valve 20 design, the annular base ring 14 is designed to substantially match the physiological shape of the inner annular wall of the vessel. The base ring 14 includes apertures 15 for purposes discussed below.

Projecting upwardly from annular ring 14 are three 25 equally spaced apart frame posts 18, 20 and 22, respectively, defining means for supporting the upper valve frame structure of valve stent 10. As illustrated more clearly in cross-sectional views in Figures 4 through 30 6, each of the post members 18, 20 and 22 would include a broadened base portion 19, a vertical post member 21 and an upper portion 23, with the lower most portion 19 of each post injection molded into annular ring 14, and the upper portion 23 of each post 18, 20 and 22, injection molded into the juncture 29 between the scallops of upper 35 ring 25. Holes 19A are inserted in the post member to

serve as anchors when the post members are injection molded into the annular ring 14 and the upper ring 25.

For purposes of construction, each of the spring steel portion of each posts 18, 20 and 22 would 5 approximate 0.001 to 0.010 inches in thickness.

With reference to the preferred embodiment, upper scalloped ring 25 would include tri-segmented scalloping rings 26, 28 and 30, each generally defining a parabaloid shaped one-third portion of the base of the valve between 10 the center lines of the respective valve posts, together forming a right cylinder of the inside diameter of valve 10. Therefore, each of the posts 18, 20 and 22 would define a means for supporting the upper ring 25 at the juncture between the three parabaloid-shaped scalloped 15 rings 26, 28 and 30, so that the lower most portion 31 of each of the scalloped rings are supported a distance 27 away from the base ring 14 as seen, for example, in Figure 1. In addition, as seen in Figure 4, because the posts are constructed of a flexible steel, when pressures are 20 exerted on the cusps of the valve, the flexible posts 18, 20 and 22 are able to flex, as seen in phantom view in Figure 4, thus extending the life of the valve.

For purposes of construction, it should be noted that 25 annular ring 14 and upper ring 25, defined by the three parabaloid shaped scalloped rings 26, 28 and 30, are constructed of a polymer and spring steel composite, known under the trademark of "ELIGOY," owned by Eligiloy Co., with the spring steel leg members injection molded in place at the base 19 of annular ring 14 and at the upper 30 portion 23 at each juncture 29 of the three scalloped rings 26, 28 and 30. It has been determined that this polymer and spring steel composite structure of the valve stent achieves complete flexibility of the valve stent yet avoids any polymer creep which is a recurring problem in 35 the present state of the art.

In order to further assure that distance 27 is maintained between ring 14 and the lower most portion of

each of the scalloping rings, as seen in side views in Figures 1 and 2, base ring 14 provides three rises 32 along its length, each rise 32 constituting the point that each leg member 18, 20 and 22 is injection molded into base ring 14. Intermediate each rise 32 there is included a dip 33 in the ring. Each dip 33 corresponds to a point at which the lower most portion 31 of each scalloping ring is situated. Therefore, each dip 33 along the base ring 14 is coincidental with the lower most point 31 of each scalloping ring and assures that distance 27 will be maintained between the base ring 14 and the lower most point 31 of each scalloping ring 26, 28 and 30, so that greater flexibility between base ring 14 and the scalloping rings is maintained.

As is further illustrated in Figures 7, 8 and 9, a tricuspid valve body 44 is shown supported by valve stent 10. The body 44 is constructed over stent 10 using state-of-the-art techniques well known to those skilled in the art. Constructed around annular base ring 14 and scalloping rings 26, 28 and 30 is a skirt portion 46 which is sutured onto the heart tissue surrounding the aortic valve annulus in the case of a heart valve or the walls of the vessel in the case of a vascular valve. One end of the skirt portion 46 is attached to the base ring 14 and sutured through aperatures 15. The other end of skirt portion 46 is sutured to the scalloped rings 26, 28 and 30 through aperatures 70. The skirt portion 46 is attached to the scalloped rings to provide a wrapped portion L as shown in Figure 9 which is the part of skirt portion 46 sutured to the aortic valve annulus or the vessel wall. This maintains the valve securely in position. The wrapped portion L includes a fabric filler 71 to give the portion L body. The fabric filler may be made of any durable yet inert material such as Dacron<sub>®</sub> or Teflon<sub>®</sub>. It should be noted that even in spite of securing the valve 10 in position, the design allows free movement of three

scalloping rings 26, 28 and 30, therefore providing greater flexibility of the upper valve body during blood flow through the valve.

Figures 10 and 11 illustrates the alternate 5 embodiment of the bioprosthetic valve of the present invention. Illustrated therein is a valve stent represented by the numeral 110. The valve stent 110 would comprise a valve frame assembly 112, with the valve frame assembly 112 including a lowermost annular base ring 114. 10 Again, the annular base ring 114 is designed, in the case of the heart valve, to substantially match the physiological aortic valve annulus shape corresponding to the inflow orifice. In the case of a vascular valve design, the annular base ring 114 is designed to 15 substantially match the physiological shape of the inner annular wall of the vessel.

Projecting upwardly from the annular base ring 114 are two equally spaced apart frame posts 118 and 120 which define means for supporting the upper valve frame 20 structure. Each of the post members 118 and 120 would include a broad portion, a vertical member and an upper portion similar to base portion 19, vertical post member 21 and upper portion 23 as shown in Figures 4-6 of the preferred embodiment. Again, the upper portion of each 25 post 118 and 120 would be injection molded into the juncture 129 between the scallops of outer ring 125.

The upper scallop ring 125 would include bisegmented scalloped rings 126 and 128, each generally defining a parabolic-shaped one-half portion of the base of the valve 30 between the center lines of the respective valve posts, together forming a right cylinder of the inside diameter of the valve. As discussed above with respect to the preferred embodiment, the construction would be of a polymer and spring steel composite.

35 Furthermore, as discussed above with respect to the preferred embodiment, the distance 127 between the ring 114 and the lowermost portion 131 of each of the scalloped rings would be maintained by providing the base ring 114

with two rises 132 along its length. As in the preferred embodiment, intermediate each rise 132 there is included a dip 133 wherein each dip 133 corresponds to a point at which the lowermost portion 131 of each scalloped ring is 5 situated. This assures that the distance 127 will be maintained between the dip 133 of base ring 114 and the lowermost point 131 of each scalloped ring 126 and 128.

Other than the structural differences associated with the use of two posts, as opposed to three posts, the 10 construction and performance of the alternate embodiment is identical to that of the preferred embodiment.

The valve stent of the present invention may be utilized to replace a defective aortic valve such as the aortic or mitral valves. Under normal circumstances, the 15 stent would be cloth covered with a tricuspid valve body 44. In the case of the preferred embodiment, three apices of the tri-segmented valve body define the three valve cusps, as are present in the natural aortic valve. Since the aortic and pulmonary valves are similar in configuration as are the mitral and tricuspid valves, and since the 20 valve stent referred to herein as an aortic valve stent is equally suited to the pulmonary valve location, it is to be understood that the terms aortic and mitral are descriptive of the type of application and are not 25 restrictive to a particular anatomical location. For example, as discussed above, the valve may be of a general vascular type for use in a vein or other anatomical vessel. In the case of the alternate embodiment, the stent would 30 be cloth covered with a bicuspid valve body and the two apices of the bi-segmental valve body define the bicuspid valve arrangement. Its use would be similar to that of the preferred embodiment.

Because many varying and different embodiments may be made within the scope of the inventive concept herein taught, and because many modifications may be made in the 35 embodiments herein detailed in accordance with the descriptive requirement of the law, it is to be understood

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that the details herein are to be interpreted as  
illustrative and not in a limiting sense.

What is claimed as invention is:

1        1. A valve stent, comprising:  
2            a. a frame assembly having a central flow  
3            orifice;  
4            b. a base ring on the frame assembly  
5            surrounding a valve annulus so that the flow orifice can  
6            register with the valve annulus;  
7            c. an upper ring, including a plurality of  
8            substantially parabolic-shaped scalloped rings, each  
9            defining a portion of the frame assembly and joining at  
10            respective apices spaced from the lower ring; and  
11            d. at least two leg members for flexibly  
12            supporting the parabolic-shaped scalloped ring a distance  
13            above the base ring.

1        2. The valve stent in Claim 1, wherein said valve  
2            stent further comprises means for attaching the frame  
3            assembly to heart tissue surrounding the valve annulus.

1        3. The valve stent in Claim 1, wherein said valve  
2            stent comprises at least three leg members and said upper  
3            ring includes at least three substantially  
4            parabolic-shaped scalloped rings, each defining an  
5            approximate one-third portion of the frame assembly.

1        4. The valve stent in Claim 3, wherein the parabolic  
2            shaped scalloping rings further define a one-third portion  
3            of the base between the center line of the leg members to  
4            form a right cylinder of the inside diameter of the valve.

1        5. The valve stent in Claim 1, wherein the base ring  
2            and upper rings are constructed of a polymer and spring  
3            steel composite.

1        6. The valve stent in Claim 1, wherein the leg  
2            members are injection molded into the base ring and into  
3            the upper ring member.

1        7. The valve stent in Claim 1, wherein the base ring  
2 further defines a circular inflow orifice substantially  
3 the shape of an aortic valve orifice.

1        8. The valve stent in Claim 1, wherein each leg  
2 member is comprised of flexible spring steel for defining  
3 a support means between the base ring and the upper  
4 scalloped ring.

1        9. The valve stent in Claim 1, wherein the flexible  
2 leg members provide greater flexibility to the upper  
3 scalloped rings during operation of the valve.

1        10. The valve stent in Claim 1, wherein there is  
2 further provided a tricuspid valve body constructed over  
3 the frame for operation of the valve.

1        11. A tissue valve stent, comprising:

2            a. a frame assembly having a central flow  
3 orifice;

4            b. a base ring on the frame assembly  
5 surrounding a valve annulus so that the flow orifice can  
6 register with the valve annulus;

7            c. an upper ring, including a plurality of  
8 substantially parabolic-shaped scalloped rings, each  
9 defining an approximate one-third portion of the frame  
10 assembly and joining at respective apices spaced from the  
11 lower ring; and

12            d. two leg members for flexibly supporting the  
13 parabolic-shaped scalloped ring a distance above the base  
14 ring.

1        12. The valve stent in Claim 11, wherein said valve  
2 stent further comprises means for attaching the frame  
3 assembly to heart tissue surrounding the valve annulus.

1        13. The valve stent in Claim 11, wherein there is  
2 further provided a tricuspid valve body constructed over  
3 the frame for operation of the valve.

1        14. A tissue heart valve, comprising:  
2                a. a frame assembly;  
3                        b. a ring on the base of the frame assembly  
4                        having an orifice substantially the shape of an aortic  
5                        valve inflow orifice;  
6                        c. at least three equally spaced apart post  
7                        members secured at their lower most portion to the base  
8                        ring, and extending vertically to a point above the base  
9                        ring; and  
10                        d. an upper frame body, further comprising a  
11                        plurality of paraboloid-shaped scalloped rings, secured to  
12                        and extending between each post member for defining a  
13                        tri-segmented scalloped ring.

1        15. The valve in Claim 14, further comprising means  
2                for attaching the frame to heart tissue surrounding the  
3                valve annulus.

1        16. A valve in Claim 14, wherein the three equally-  
2                spaced post members are secured at their lower most end to  
3                the base ring and at their upper most end to the  
4                parabolic-shaped rings by injection molding.

1        17. The valve in Claim 14, wherein the post members  
2                are constructed of spring steel for providing the flextral  
3                capability for allowing relative movement between the  
4                scalloped ring and the annular ring.

1        18. The valve in Claim 15, wherein the means for  
2                attaching the base ring to heart tissue further includes a  
3                suture ring constructed around the annular base ring.

1        19. The valve in Claim 14, further comprising a  
2                fluid valve body mountable on the upper scalloped ring,  
3                for defining a one-way passage for blood flowing  
4                therethrough.

1        20. A bioprosthetic valve stent for supporting a  
2        valve body, comprising:  
3                a. a base ring, having an inflow orifice;  
4                b. an upper multi-segmented parabolic-scalloped  
5        ring, providing at least two equally spaced apart valve  
6        segments; and  
7                c. at least two post members extending between  
8        the annular base ring and the upper most portion of the  
9        scalloped rings, for providing flextral capability  
10      allowing relative movement between the scalloped rings and  
11      the annular base ring.

1        21. A tissue heart valve stent for supporting a  
2        valve body and mountable on the tissue surrounding the  
3        valve annulus, comprising:  
4                a. a base ring, having an inflow orifice  
5        substantially the shape of a heart valve;  
6                b. an upper tri-segmented parabolic-scalloped  
7        ring, providing three equally spaced apart valve segments;  
8        and  
9                c. a plurality of post members extending  
10      between the annular base ring and the upper most portion  
11      of the scalloped rings, for providing flextral capability  
12      allowing relative movement between the scalloped rings and  
13      the annular base ring.

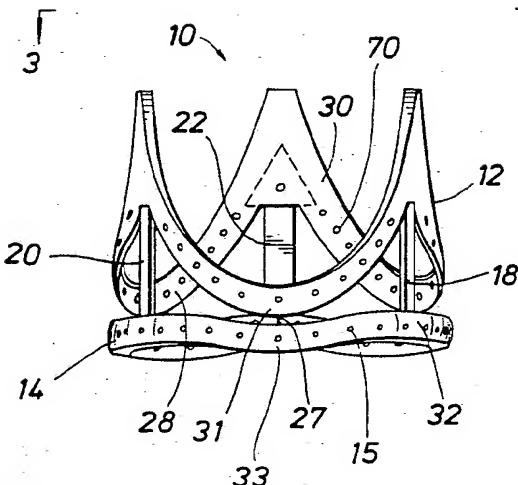


FIG. 1

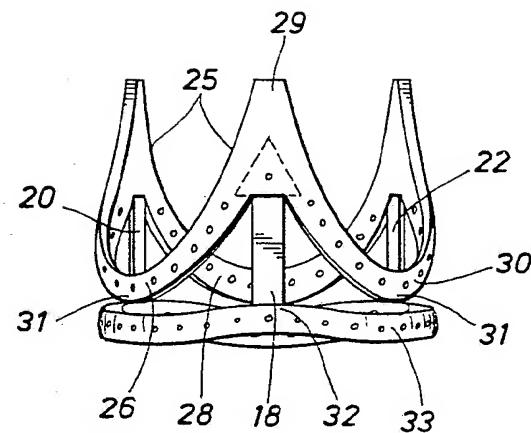


FIG. 2

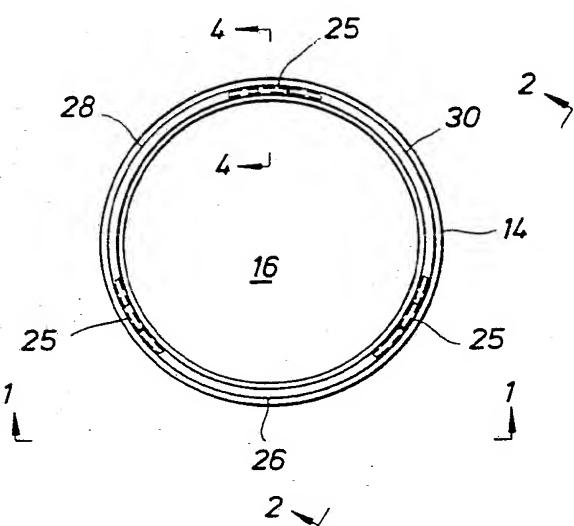


FIG. 3

FIG. 4

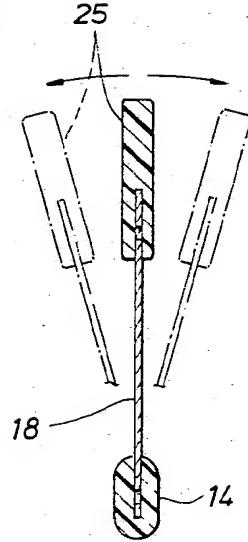


FIG. 5

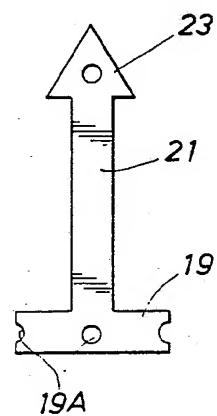
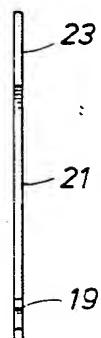


FIG. 6



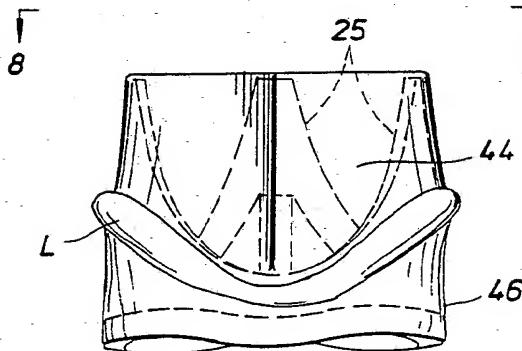


FIG. 7

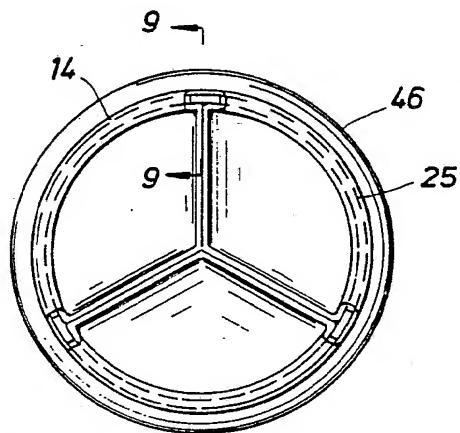


FIG. 8

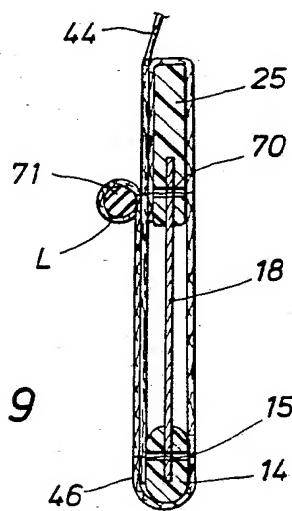


FIG. 9

FIG. 10

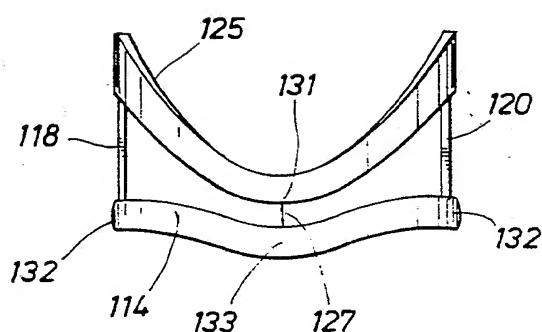
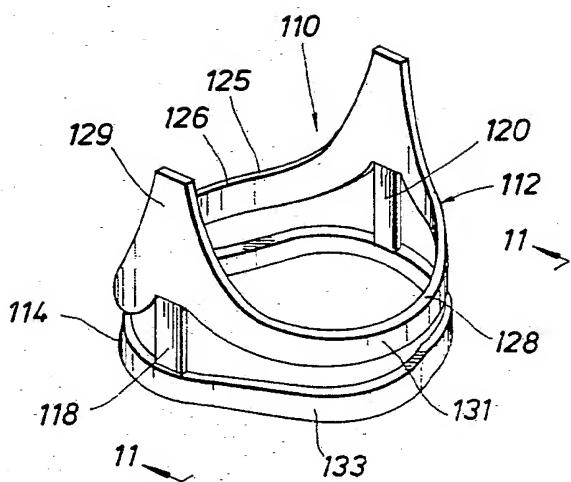
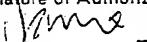


FIG. 11

# INTERNATIONAL SEARCH REPORT

International Application No. **PCT/US88/02041**

<b>I. CLASSIFICATION OF SUBJECT MATTER</b> (if several classification symbols apply, indicate all) <sup>6</sup>		
According to International Patent Classification (IPC) or to both National Classification and IPC		
<b>IPC (4) A61F 2/24</b>		
<b>U.S. CL 623/2</b>		
<b>II. FIELDS SEARCHED</b>		
Minimum Documentation Searched <sup>7</sup>		
Classification System	Classification Symbols	
US	623/2	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched <sup>8</sup>		
<b>III. DOCUMENTS CONSIDERED TO BE RELEVANT</b> <sup>9</sup>		
Category <sup>10</sup>	Citation of Document, <sup>11</sup> with indication, where appropriate, of the relevant passages <sup>12</sup>	Relevant to Claim No. <sup>13</sup>
X	US, A, 3,755,823 (HANCOCK) 04 September 1973 See Figure 3 and column 1, lines 25-45	1-21
<p>* Special categories of cited documents: <sup>10</sup></p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&amp;" document member of the same patent family</p>		
<b>IV. CERTIFICATION</b>		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
08 September 1988	11 OCT 1988	
International Searching Authority	Signature of Authorized Officer	
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